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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,856	12/02/2003	Shiguang Yu	2664H-000059/US	3241

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EXAMINER

EBRAHIM, NABILA G

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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01/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/725,856	Applicant(s) YU ET AL.	
	Examiner Nabila G. Ebrahim	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 37 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/24/2008 has been entered.

Status of Claims

Claims 1-14 and 37-38 are pending in the application.

Claims 15-36 were canceled.

Status of Office Action: Non-Final.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 10-12 and 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Morris et al. US publication 20010014442 (Morris).

Morris teaches consumable product utilized to maintain and restore hair color comprises a substrate and an effective amount of a directly available amino acid (in pure or diluted form) wherein the directly available amino acid is selected from the group consisting of tyrosine, phenylalanine and mixtures thereof (abstract). The effective amount of directly available tyrosine may be at least approximately 0.05% by weight of the diet [0019]. Also adding an effective

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amount (e.g., at least approximately 0.05% by weight, or at least approximately 0.1% by weight) of a directly available amino acid selected from the group consisting of tyrosine, phenylalanine and mixtures thereof or to an animal consumable product having indirectly available amino acids therein to produce a supplemented consumable [0021], it is noted that the range disclosed by Morris is overlapping with range required in instant claims 1-3. The composition is provided to animals such as e.g., a cat, a dog, or mink, etc. [0026]. The food can be gelatin based [0030, 0037, 0038, and 0041]. Morris also discloses that milk contains proteins supplying adequate amounts of phenylalanine and tyrosine for melanin synthesis [0047]. The animal food can be in a dry matter [0036, 0047].

2. Claims 1-2, 13-14, and 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Kempen US 6004614 (Kempen).

Kempen teaches animal feed ingredients containing dicarboxylic acids. Three experiments were carried out to evaluate the effectiveness of adipic acid in animals weight gaining. One of the compositions used in the experiments comprises tyrosine in an amount of 0.15 (see table in col. 2).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-14, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morris et al. US publication 20010014442 (Morris) or Kempen US 6004614 (Kempen) in view of Gerth et al US 5925377 (Gerth) and further in view of Nagaoka Satoshi et al., Effects of excess dietary tyrosine on cholesterol, bile acid metabolism and mixed-function oxidase system in rats, J Nutr. 1990 Oct;120(10):1134-9.

Morris and Kempen are relied upon for the reasons set forth hereinabove.

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Further, Morris discloses the use of fat, cellulose (fibers), carbohydrate (sucrose and starch), and protein in the animal food [abstract, and table 3]. Morris did not disclose the amounts recited in claims 5 and 9; however, animal foods ingredients such as proteins, carbohydrates, fats, and dietary fibers are conventional ingredients that are known to be used in many different amounts and ranges. Kempen discloses the use of carbohydrate, protein and fat containing ingredients (see tables in columns 2 and 3). Note that once a method of using an ingredient is known it is within the skill of the skilled artisan to determine the optimum amounts to use and the optimum end points in using the ingredient.

Morris and Kempen are deficient in disclosing the use of the composition for weight loss and also the improvement of the method of use by reducing the amount of tyrosine.

Gerth teaches that a dietary supplement composition wherein DL-phenylalanine is combined with tyrosine to act as an appetite depressant (abstract).

It would have been obvious to one of ordinary skill in the art to combine the disclosures of Morris or Kempen and Gerth to control the obesity problems in animals/humans.

None of the references discloses the reason why a skilled artisan would be motivated to lower the amount of tyrosine.

Satoshi teaches that the excess dietary tyrosine causes hypercholesterolemia and affects bile acid metabolism and mixed-function oxidase system (title and abstract).

The reference does not specify that the amount of tyrosine used should not exceed the ranges recited in the instant claims. However, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of tyrosine in order to best achieve the desired results.

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Accordingly, it would have been obvious to one of ordinary skill in the art to reduce the amount of tyrosine used by Gerth to the least amount that may be useful to control appetite and assists in weight loss in animals and reduce any side-effects that may result from the use of higher tyrosine. The expected results would be a composition that includes tyrosine in a least amount that may cause appetite suppression as the overlapping amount disclosed by Morris and Kempen, phenylalanine, carbohydrate, protein, fat, and dietary fibers. The skilled artisan would be motivated to lower the amount disclosed by Gerth because of the research disclosed by Satoshi that excess amount of tyrosine would increase blood cholesterol. The skilled artisan would have expectation of success of having a dietary supplement comprising tyrosine that reduces weight and is improved to include less amounts of tyrosine.

Response to Arguments

3. Applicant's arguments filed 3/24/2008 have been fully considered but they are not persuasive.

Claim Rejection under 35 U.S.C. §102:

- Applicant arguments is based on alleging that Morris disclosure of the amount of tyrosine is not sufficiently overlapping with the range recited in claim 1.

To respond: the range taught by Morris overlaps with the range recited by the instant claims.

Claim 1 recites a range which does not exceed 0.4%. Morris disclosed a range of at least approximately 0.05% by weight, or at least approximately 0.1%, accordingly, the two ranges are overlapping. Further, the argument renders moot in view of relying upon Kempen.

Claim Rejection under 35 U.S.C. §103:

Applicant argues that:

- The cited references fail to teach any compositions comprising tyrosine in an amount not to exceed about 0.4%.

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To respond: Applicant's arguments regarding the amount of tyrosine renders moot in view of the disclosure of Kempen. It is also noted that Satoshi Nagaoka is clear regarding administering high tyrosine compositions since the reference teaches that excess dietary tyrosine causes hypercholesterolemia and affects bile acid metabolism and mixed-function oxidase system (see title and abstract).

- Neither references (Morris and Gerth) teach why one of skill in the art would be motivated to lower the amounts of tyrosine.
- One of ordinary skill in the art would not be motivated or have a reasonable expectation of success of practicing the claimed invention unless they recognized that compositions containing no more than 0.4% tyrosine are effective in reducing body weight.

Nagaoka et al., which the Examiner asserts would motivate one of skill in the art to reduce excess dietary tyrosine, provides no guidance or motivation as to what amounts of tyrosine are desirable, other than to suggest that excess amounts of tyrosine are to be avoided.

To respond, the amounts disclosed by Morris are overlapping with the amounts of the instant claims. The amounts disclosed by Kempen are encompassed by the amounts recited in instant claims 1 and 2. Further, Nagaoka teaches clearly that excess dietary tyrosine causes hypercholesterolemia and affects bile acid metabolism and mixed-function oxidase system.

Thus the person of ordinary skill would routinely experiment the correct amount of tyrosine that may be administered and would not harm the system of a subject receiving tyrosine containing compositions. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to choose from a finite number of predictable amounts of tyrosine following prior art such as Kempen with a reasonable expectation of success of producing a tyrosine containing formulation that would not be harmful to the system of the recipient.

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- Nagaoka et al. is limited to the dietary effects of excess tyrosine, and does not teach or suggest any benefit to limiting amounts of tyrosine to levels less than excess amounts.

To respond: Nagaoka raises the red flag for raising the amounts of tyrosine in compositions, however, it is noted that determining the correct amounts is within a person of ordinary skill in the art.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nabila G Ebrahim/
Examiner, Art Unit 1618

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit
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